



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/731,867

12/09/2003

Carl D. Wahlstrand

1023-336US01

6722

28863 7590 04/04/2008
SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER

REIDEL, JESSICA L

ART UNIT

PAPER NUMBER

3766

NOTIFICATION DATE

DELIVERY MODE

04/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary	Application No. 10/731,867	Applicant(s) WAHLSTRAND ET AL.	
	Examiner JESSICA REIDEL	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-22, 28-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-22, 28-31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/06, 8/07, 1/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on January 3, 2008. Claims 11, 23, 24, 26 and 27 have been cancelled. Claims 25 and 32 were previously cancelled. Claims 1-10, 12-22, 28-31, 33 and 34 are pending.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on February 22, 2006, August 16, 2007 and January 3, 2008 have been acknowledged and are being considered by the Examiner.

Oath/Declaration

3. In view of the response filed January 3, 2008, the objection(s) applied against the Oath/Declaration in the Office Action of September 7, 2007 have been withdrawn.

Specification

4. In view of the response filed January 3, 2008, the objection(s) applied against Applicant's disclosure in the Office Action of September 7, 2007 have been withdrawn.

Claim Objections

5. Claims 1, 7, 18, 19, 21, 29, 30 and 33 are objected to because of the following informalities: inadvertent typographical and/or grammatical errors exist rendering the language awkward and/or ambiguous. As to Claims 1 and 30, the Examiner suggests changing lines 2-3 of these claims to read something similar to, "a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings wherein at least one of the respective housings is metallic;" in order to avoid 35 U.S.C. 112, second paragraph issues against any dependent claims which further define any of the respective housings of any one of the modules. Also, all recitations of "the housing" within Claims 18, 19, 21 and 29 should be changed to read, "the metallic housing" instead in order avoid antecedent basis problems. As to Claim 7, line 3, the Examiner suggests changing "radius of the arc" to read, "radius of the arc"

Art Unit: 3766

instead. As to Claim 33, line 2, the Examiner suggests changing “located within the housing of one of” to read, “located within a housing of one of” instead. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

7. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

8. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: “two modules, each comprising a metallic housing”. Claim 12 currently defines an overmold which does not encapsulate “a portion of each of at least two metallic housings of the plurality of interconnected modules”, however, neither of Claims 1 or 12 define a device comprising at least two interconnected modules, each of the two modules having a respective metallic housing. The Examiner suggests revising Claim 12 to read something similar to, “The implantable medical device of Claim 1, wherein at least two of the modules comprise metallic housings; and wherein the overmold does not encapsulate a portion of each of the at least two of the metallic housings” to overcome this rejection.

9. Claim 13 recites the limitation “the housing that is adapted to be implanted proximate to the cranium”. There is insufficient antecedent basis for this limitation in the claim. Although Claim 1 defines that a surface of the overmold “is adapted to be implanted proximate to a cranium”, neither of Claims 1 or 13 define that any one of the respective housings of the interconnected modules comprise a surface that is adapted to be implanted proximate to a cranium”. The Examiner suggests changing Claim 13 to read something similar to, “The implantable medical device of Claim 1, wherein a surface of each of the respective housings is concave along at least one axis prior to manipulation of the implantable medical device and is adapted to be implanted proximate to the cranium” in order to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-10, 12-22, 28-31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys et al. (U.S. 6,308,101) (herein Faltys) in view of Probst et al. (U.S. 2003/0017372) (herein Probst). As to Claims 1-6, 10, 13, 18, 22 and 29, Faltys expressly discloses a partitioned implantable cochlear implant system, read as an implantable medical device (IMD) 160 comprising a plurality of interconnected modules (i.e. an implantable cochlear stimulator (ICS) 112' and an implantable speech processor/power (SP/PWR) unit 162). Faltys specifies that the SP/PWR unit 162 may comprise a metallic hermetic housing of titanium, stainless steel, or other similar material that is compatible with body tissue (see Faltys Figs. 1E, 3A and 3B and column 12, lines 17-55). Additionally, the ICS 112' module comprises an analog chip, read as a therapy delivery element U1 and a gate array chip, read as control electronics U2, both the therapy delivery element U1 and control electronics U2 being within a hermetic ceramic housing of the ICS 112' module. Therapy delivery element U1 includes circuits for providing stimulation currents, voltage regulation, and bi-directional telemetry modulation and control electronics U2 controls the delivery of the stimulation current and the bi-directional telemetry (see Faltys Fig. 8B, column 17, lines 57-67 and column 18, lines 1-7). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference

Art Unit: 3766

between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If a prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, since the IMD 160 of Faltys is implantable beneath the scalp of a patient and since the therapy delivery element U1 provides current for driving implantable electrodes of an electrode array 114, the therapy delivery element U1 is capable of delivering stimulation therapy to a brain of a patient. Furthermore, Faltys expressly discloses that the partitioned IMD 160, as previously discussed, “may be applied to other implantable neural or muscular stimulation devices, or other implantable devices”, in addition to its disclosed cochlear application (see Faltys column 20, lines 65-67 and column 21, lines 1-10).

The IMD 160 of Faltys further comprises a coil 172 embedded within a silicone rubber encasing mold 174. The Examiner considers the encasing mold 174 of Faltys synonymous with Applicants claimed “overmold” since the mold 174 is “formed so as to adhere to the sides” of the SP/PWR unit 162 and the ICS 112' module and because, upon inspection of Faltys Figs. 3A and 3B, the mold 174 appears to “at least partially encapsulate” each of the modules and the modules are horizontally distributed at respective locations of the mold 174. The Examiner also considers the modules as being “separately encapsulated” by the mold 174 since the modules are separated or partitioned (see Faltys Figs. 3A and 3B). Faltys discloses the claimed invention, as previously discussed, except that it is not specified that the overmold 174 be formed such that a surface of the overmold is concave along at least two axes prior to manipulation of the IMD 160 such that the surface is adapted to be implanted proximate to a cranium of the patient and to conform substantially to the cranium.

Probst, however, teaches an IMD 10 (i.e. a neurostimulator, pacemaker, defibrillator) housing comprising opposed major sidewalls 62, 64 of a contoured shape (see Probst Figs. 1-4 and 6-8) and an inner power source module 12 housing 14, also having opposed sidewalls 16, 18 of a contoured shape (see Probst Fig. 1) such that areas of the body, such as the skull, do not have to be invasively and/or unnecessarily excavated in order to facilitate implantation of the IMD. Specifically, the IMD 10 of Probst comprises a housing manufactured such that opposing surfaces conform substantially to an arc, where at least a first surface is concave along multiple axes and the second opposing surface is convex and distal from the first surface and the implantation site (i.e. the cranium). The housing components of Probst conform substantially to

Art Unit: 3766

an arc (see Probst Figs. 7-8 and page 3, paragraphs 36-42) prior to manipulation of the IMD 10 such that the surfaces are adapted to be implanted proximate to a cranium, to conform substantially to the cranium (see Probst Abstract, pages 1-2, paragraphs 2-4 and paragraphs 21-24). IMD 10 of Probst also comprises housing 14 of module 12, identical to that of the housing of the entire IMD (see Probst page 1, paragraphs 16-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold 174 and the housings modules 162, 112' of the partitioned IMD 160 taught by Faltys, such that a surface of each is concave along multiple axes as taught by Probst, such that the overold 174 and the modules 162, 112' conform substantially to an arc, prior to manipulation of the IMD 160, in order to provide an improved IMD 160 adapted to be implanted proximate the cranium of the patient, to conform substantially to the cranium and further such that the IMD 160 may be easily implanted without undo excavation of the implant site.

13. As to Claims 7, 9, 19 and 21, the modified Faltys reference discloses the claimed invention, as previously discussed, except that it is not specified that the arc be within a range from 4.5-9.5 centimeters. Since Probst expressly discloses that the device may be implanted proximate the skull, on the skull, or within the skull, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of Faltys in view of Probst be within a range from 4.5 to 9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

14. As to Claims 8 and 20, the previously modified Faltys reference discloses the claimed invention, as discussed above, except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

15. As to Claim 14, in addition to the arguments previously presented, Faltys expressly discloses that the module comprising the metallic housing, specifically the SP/PWR unit 162, is a control module that includes control electronics. In particular, Faltys expressly discloses that the SP/PWR unit 162 may include an analog front end (AFE) circuit U4, which is a microphone

Art Unit: 3766

control circuit 240, a gate array chip U3, and a processor chip U5 (see, for example, Faltys Fig. 8A, column 16, lines 46-67 and column 17, lines 27).

16. As to Claims 15, 16 and 33, in addition to the arguments previously presented, Faltys expressly discloses that the module comprising the metallic housing, specifically the SP/PWR unit 162, is a power source module that may include a rechargeable lithium-Ion (Lion) battery 216, or other types of batteries or replenishable power sources, such as ultracapacitors (see, for example, Faltys column 3, lines 62-67, column 4, lines 1-65, column 5, lines 1-18, column 8, lines 45-67, column 9, lines 32-48 and column 15, lines 49-65). The previously modified Faltys reference discloses the claimed invention, as discussed above, except it is not specified that the battery of the IMD 160 have a wound coil construction or a foil pack construction. It would have been obvious to one having ordinary skill in the art at the time the invention was made, however, to modify the battery of Faltys in view of Probst to have either a wound coil construction or a foil pack construction, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See *In re Leshin*, 125 USPQ 416.

17. As to Claim 17, in addition to the arguments previously presented, Faltys expressly discloses that the module comprising the metallic housing, specifically the SP/PWR unit 162, is a recharge module including a recharge coil 172 for inductively receiving energy (see, for example, Faltys Figs. 3A and 3B and column 12, lines 17-55).

18. As to Claims 12 and 28, in addition to the arguments previously presented, Faltys indicates that a ceramic, or equivalent material, is used for the case material of the ICS 112' module, to facilitate magnetic coupling through the case. Faltys further specifies that "a metal header 115 is hermetically sealed to one end of the ceramic case", thus the Examiner considers the housing of the ICS 112' as "metallic". Overmold 174 does not encapsulate the metal header 115 portion of the ICS 112' module housing (see Faltys Figs. 3A and 3B and column 12, lines 17-41).

19. As to Claims 30, 31 and 34, in addition to the arguments previously presented, since the overmold 174 of Faltys is made of a flexible silicone rubber, the overmold 174 "is configured to allow relative motion between the plurality of interconnected modules" (i.e. ICS 112' and SP/PWR unit 162) (see Faltys Figs. 3A and 3B and column 12, lines 17-41).

Terminal Disclaimer

20. The terminal disclaimer filed on January 3, 2008 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

21. Applicant's arguments filed January 3, 2008, with respect to Claims 1 and 30, have been considered but are moot in view of the new ground(s) of rejection.

22. Applicant's arguments filed January 3, 2008, with respect to Claims 2, 14 and 17, have been fully considered but they are not persuasive. At page 17, lines 6-13, Applicant argues that curvatures R2, R3, R4 of Probst Fig. 7 "are not curvatures along more than one axes, but merely different radii of curvature along the same axis". Although the Examiner agrees that Probst discloses different radii of curvature, the Examiner does not agree that each is along one synonymous axis that extends in the horizontal direction of Probst Figs. 6-8. A dictionary definition of the term "axes" includes "reference lines from which distances or angles are measured in a coordinate system". Therefore, in reference to Probst Fig. 7, for example, tangent points 228 and 230 define a first curved portion along an axis or reference line extending between them and tangent points 230 and 234 define a second curved portion along an axis or reference line extending between them. Since the first and second curved portions may each have a different radius of curvature (i.e. defined by R2 and R3 respectively), yielding a different degree of curvature, the axis or reference lines along which each radii moves are not synonymous with one single axis extending in the horizontal direction of Fig. 7. In response to Applicant's arguments regarding Applicant's Fig. 8B being different from that which is disclosed by Probst (see page 17, lines 2-5 of the Remarks), the Examiner suggests modifying the language of the claims such that it is clear that the concavity exists along two axes, the two axes being *perpendicular to each other* (emphasis added).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Art Unit: 3766

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JESSICA REIDEL whose telephone number is (571)272-2129. The Examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
March 23, 2008

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
March 26, 2008